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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,260	03/26/2001	Nicholas J. Schork	GENSET.076C1	9223
23557 7590 01/30/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	09/818,260		SCHORK ET AL.	
	Examiner		Art Unit	
	Jerry Lin		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7, 40, 41 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, 40, 41, 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2006 has been entered.

Applicants' arguments and amendments, filed, September 11, 2006, have been fully considered and they not persuasive. The following rejections are reiterated. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1, 4, 7, 40, 41, and 46-50 are under examination.

Claims 2-3, 5-6, 8-39, and 42-45 are cancelled (claims 8-39 are drawn to an unelected invention).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 4, 7, 40, 41, and 46-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant method is drawn to a mathematical algorithm for determining the statistical significance of a difference between haplotype frequency profiles of at least two groups of individuals.

Instant claims 1, 4, 7, 40, 41, 46, 47-50 are drawn to a mathematical algorithm. A mathematical algorithm is a judicial exception that is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or an useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if

the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a method of determining the statistical significance of a difference between haplotype frequency profiles. The entire process may take place within a computer without any communication to the outside world. Thus the claims do not necessarily produce a real-world result. Since the claims do not necessarily produce a real-world result, the instant claims do not include any tangible result.

Instant claims 7, 48, and 49 are drawn to propagated data signals which are non-statutory *per se*.

Instant claims 4, 46, and 47 are drawn to a judicial exception that requires practical application. Including electronic computers in the claims does not prevent this requirement. As stated above, the instant claims do not have a practical application.

Response to Arguments

4. The Applicants have responded this rejection, in regards to claims 1, 40, 41, and 50, by citing Patent Office guidelines that, "If a claim requires acts to be performed to create data that will be used in a process representing a practical application of one or more mathematical operations, those acts must be treated as further limiting the claim beyond the mathematical operation(s) *per se*" The applicants then state steps (a)

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and (b) of claims 1, 40, 41, and 50 require one to create or gather data and this meets the statutory requirements of 35 U.S.C. §101. However, in the quotation by the Applicants, the claimed process must still be drawn to a practical application, regardless of the presence or absence of creating or gathering data steps. According to the MPEP §2106 (IV) (C) (2), page 2100-11, (please see http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_2100.pdf for the newest version of the guidelines) a claimed process may demonstrate a practical application by either a physical transformation or a useful, tangible, and concrete final result. As stated above, the instant claims do not have a physical transformation or a useful, tangible, and concrete final result. Thus the instant claims do not have a practical application and are not statutory.

The Examiner notes that the instant claims are drawn to the final result of determining a statistical significance of the difference. In order to comply with 35 U.S.C. §101, that final result must be useful, tangible and concrete. In order to fulfill the tangibility requirement, the Examiner suggests adding an additional step where the statistical significance of the difference is outputted to a user or where the final result is saved on a readily accessible computer medium (support for this step may be found on Figure 15 of the specification).

Applicants also state, in regards to claims 4, 7, 46, 47, 48, 49, that the claims comprise of electronically connected computers or programmed storage devices. In regards to claims 7, 48, and 49, the applicants state that programmed storage devices are any computer readable media on which a program readable by a computer has

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been stored. The Examiner notes that the applicants have defined computer readable media to include propagated data signals (page 16 of the Specification). However, according the MPEP §2106.01, data signal are non-statutory *per se*. In this case, the Examiner suggests adding the suggested step above and that data signals be removed as one of the possible embodiments of computer readable medium.

In regards to claims 4, 46, 47, the Applicants point to electronically connected computers. First the examiner notes that in the last part of each claim, the computer execute software of programs stored on the programmed storage devices. However, the instant claims do not indicate what programs are stored on the programmed storage devices. Thus the computer may execute any program and is not required to execute the instructions listed in the claim. Thus, the computer has not gained any additional function from the presence of the instructions. Secondly, the instant claims are drawn to a judicial exception that requires a practical application. As stated above, the instant claims do not have such a practical application. Thus, the instant claims are not statutory. In this case, the Examiner suggests adding the suggested step above and amending the claims to more clearly recite what the computer is executing.

Conclusion

5. This is a Request for Continued Examination of applicant's Application No. 09/818,260. All claims are drawn to the same invention claimed in the earlier office action and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first

action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written below the printed name.